

REMARKS/ARGUMENTS

Claims 9-13 are pending. Reconsideration is respectfully requested.

Applicants' representative wishes to thank Examiner Stockton for the helpful and courteous interview of April 2, 2008. As a result of the discussion, it is believed that the issues in the case have been clarified and that the prosecution of the application has been materially advanced.

The present invention relates to a method of treating impaired gastric accommodation.

Claim Amendment

Applicants have amended Claim 9 to recite that the present method is accomplished by administering the aminothiazole compound described in the claim to a human subject in need of the compound for treating impaired gastric accommodation thereby achieving relaxation of the gastric fundus. This amendment in no manner introduces new matter into the case, but clarifies that a human subject who is administered the compound is one that suffers from impaired gastric accommodation. Entry of the amendment is respectfully requested.

Claim Rejection, 35 USC 112

Claim 9 has been amended to recite the effect achieved in the present invention of relieving the impairment of gastric accommodation in a subject by relaxation of the gastric fundus in the preamble of the claim. This amendment conforms with the suggestion by the Examiner. Entry of the amendment is respectfully requested.

Obviousness-type Double Patenting

Claims 9-13 stand rejected based on obviousness-type double patenting in view of Claims 11 and 12 of Nagasawa et al, U. S. Patent 5,981,557. This ground of rejection is respectfully traversed.

Consistent with the arguments advanced by applicants' representative and on the record of the case, Claim 11 of the '557 patent is directed to a method of treating digestive dysmotility of a patient by administering the therapeutically active compound of formula (1) in the claim. Symptoms of the condition are set forth in Claim 12 and are the likes of nausea, heart burn, flatulence, gastritis, gastritus and vomiting. However, the disorder identified in Claim 11 of digestive dysmotility is not the disorder being treated by the method of the present invention which is gastric accommodation which specifically involves the fundus of the stomach. The method of the reference discloses an aminothiazole compound which is said to be effective in treating this particular condition. However, digestive dysmotility is not impaired accommodation of the gastric fundus. Moreover, the documentation previously presented of record concerning the findings and recommendations of an international body of gastroenterologists establishes that at the time of the invention of Nagasawa et al, impairment of gastric accommodation was not recognized as a gastric disorder.

The Examiner states that *one of skill in the art would be motivated to prepare products (of the patent) in order to arrive at the instant claimed products with the expectation of obtaining additional beneficial products which would be useful in treating, for example, gastric pain*. However, if the reference claims that a certain class of aminothiazole compounds is effective in treating gastric motility, and it does, how would it be obvious to one of skill in the art to use much the same compound to treat a gastric condition, which, at the time of the invention by patentees, was not only not known, but one that does not involve gastric dysmotility at all, but rather the fundus of the stomach? Accordingly, the claims of

the Nagasawa et al patent do not suggest the present invention as claimed and withdrawal of the rejection is respectfully requested.

Rejection, 35 U.S.C. §102

Claims 9-13 stand rejected under 35 U.S.C. 102(a) as anticipated by Sorbera et al.

This ground of rejection is respectfully traversed.

Applicants, by the filing of a certified copy of the original Japanese priority application and by the filing of a certified English translation of the priority document, hereby perfect the filing date of April 8, 2002 of the priority application. Accordingly, the rejection of the claims of the application is believed obviated and withdrawal of the same is respectfully requested.

Claims 9-13 stand rejected under 35 U.S.C. 102(b) as anticipated by each of Nagasawa et al., U.S. Patent No. 5,981,557, Nagasawa et al, JP10-212271 (abstract) and Nakajima et al., J. Smooth Muscle Res. 36:69. This ground of rejection is respectfully traversed.

Applicants concur that each of the cited references discloses an aminothiazole compound that possesses gastrointestinal prokinetic activity and that it is this compound which is the therapeutically active component of the present method as claimed. However, as previously stated on the record, none of the references discloses or suggests the use of the drug compound for the treatment of impaired gastric accommodation. Indeed, as established by applicants' comments on the several documents identified on the record as the "Rome" documents, the concept of gastric accommodation and treatment of impaired accommodation of the gastric fundus was not recognized until comparatively recently. Other states of gastric dysfunction. Applicants have argued a distinction between the dysfunction of gastric emptying of the gastric antrum and impaired gastric accommodation of the gastric fundus had

been identified. In the past, as the Rome documents have described, it was believed that the cause of early satiation is dysfunction of emptying of the gastric antrum. Since 2006, however, it has been recognized that early satiation is caused by impaired accommodation of the gastric fundus, not dysfunction of the emptying process of the gastric antrum. Applicants of the present invention realized that the compound employed in the present method of treatment treated the gastric fundus and improved gastric accommodation, thereby leading to the present invention as stated which is the treatment of a human subject in need of the compound used in the present method for the alleviation of gastric accommodation. The present method as claimed is therefore distinguished over the prior art which does not even recognize the concept of impaired gastric accommodation of the fundus, but rather treats other types of gastric disorders.

The facts of the present case are very similar to those in the case at issue in Jansen v. Rexall Sundown Inc., 68 USPQ2d 1154. The claim at issue was a method of treating or preventing pernicious anemia by administering a combination of folic acid and vitamin B<sub>12</sub> "to a human in need thereof." The claims were deemed to be properly construed to the administration of a compound to a human in recognized need to treat or prevent anemia.

In the infringement suit under consideration, the Federal district court properly granted summary judgment that the administration of defendant's over-the-counter dietary supplement does not infringe the claimed method of "treating or preventing" pernicious anemia by administering folic acid and vitamin B<sub>12</sub> "to a human being in need thereof," even though amounts of folic acid and vitamin B<sub>12</sub> in accused supplement are within ranges claimed in patent, since asserted claims are properly construed to require that compound be administered to a human with recognized need to treat or prevent anemia.

In the present claims, the compound is administered to a human subject in need of treatment in order to treat gastric accommodation and not some other gastric condition. Accordingly, the rejection is believed overcome and withdrawal of the rejection is respectfully requested.

Claims 9-13 stand rejected under 35 U.S.C. 103(a) as obvious over of Nagasawa et al., U.S. Patent No. 5,981,557 and Nagasawa et al., JP10-212271 (abstract). This ground of rejection is respectfully traversed.

Applicants traverse the obviousness ground of rejection that has been raised for the same reasons discussed immediately above. The present claims make it clear that to treat impaired gastric accommodation, the active compound of the claims is administered to a human subject in need of treatment by the drug. On the other hand, the two references disclose a method of treating digestive dysmotility, and nothing about treating impaired gastric accommodation which was not recognized as a gastric disorder at the time of the invention of Nagasawa et al. Accordingly, withdrawal of the outstanding ground of rejection is respectfully requested.

In view of the amendments and remarks above, the Applicants submit that this application is now in condition for allowance. An early notification to such effect is respectfully requested.

Respectfully submitted,

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